UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,500	06/04/2001	John E. Ware	QMET-201	5112

24972 7590 11/14/2008
FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
LE, LINH GIANG	

ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/873,500
Filing Date: June 04, 2001
Appellant(s): WARE et al.

C. Andrew Im
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 26 October 2008 appealing from the Office action mailed 11 February 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. In addition, a new ground of rejection is as follows:

NEW GROUND(S) OF REJECTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-15, 17, 35-38, 41- 42, and 44 are rejected under 35 USC 101 as these claims are directed to non-statutory subject matter. A claimed process is patent eligible under 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing. Independent claims 1 and 35 are directed towards a method of assessing the health status or health care of a patient. There is no tie to a machine or apparatus in the body of the claim nor is there a transformation of a particular article towards a different state or thing. Thus the claims are directed towards a patent-ineligible process under 35 USC 101. Furthermore, a nominal recitation in the preamble of structure in an otherwise ineligible method fails to make the process statutory.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5059127	LEWIS	10-1991
6067523	BAIR	5-2000
Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, *Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures*, The Quality of Life Newsletter		4-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(New Grounds) Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-15, 17, 35-38, 41- 42, and 44 are rejected under 35 USC 101 as these claims are directed to non-statutory subject matter. A claimed process is patent eligible under 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing. Independent claims 1 and 35 are directed towards a method of assessing the health status or health care of a patient. There is no tie to a machine or apparatus in the body of the claim nor is there a transformation of a particular article towards a different state or thing. Thus the claims are directed towards a patent-ineligible process under 35 USC 101. Furthermore, a nominal recitation in the

preamble of structure in an otherwise ineligible method fails to make the process statutory.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6, 8-23, 25-27, and 29-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), in view of Lewis (5,059,127).

5. As per claim 1, Ware teaches a method of assessing the health status or health care of a patient, comprising the steps of:
generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a

plurality of questions for said patient in accordance with said selected health domains (Ware; pg. 11, col. 2-3; pg. 12, cols 1-3);
administering said test by providing one question at a time to said patient; and
after each question (Ware; pg. 12, Col.1);
evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (Ware; pg. 11, col. 3, par. 2; pg. 12 Col.1-2; pg. 13 Col. 1-2;)

Ware does not expressly teach:
varying a threshold as a function of said estimated score; and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside a said threshold.

As per the recitation of "the threshold varying as a function of the estimated Score," Ware discloses the following steps in Figure 3: step 3) re-estimating the score, step 4) re-estimating the confidence interval, step 5) determining whether a stopping rule is satisfied and determining whether the score has been estimated within a preset standard of precision based on the confidence interval, wherein once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be a form of "threshold"), wherein the precision standard based on the confidence interval (i.e., the threshold) is set based on each patient's score (see

page 12, col. 1-2). Note, Ware's discussion of where the preset standard of precision is +/- 5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients for psychiatric disorders. Note, Ware discloses that the standard of precision was relaxed to +/- 7.9 or less for patients at or above the 90th percentile. (See page 12, col. 1 bottom to top of col. 2). From this disclosure that Ware teaches that the threshold (i.e., precision standard based on the confidence interval) varies as a function of the estimated score.

Furthermore, Lewis teaches a similar concept. In particular, Lewis teaches both random and adaptive testlet selections are well known in the art (Lewis; Col. 6, "Random vs. Optimum Selection"). Lewis teaches that the method of assigning variable threshold variables to particular testlets. It would have been obvious to add these features to the teachings of Ware with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

6. As per claim 2, Ware teaches further comprising the step of generating a report regarding the health status of said patient (Ware; pg. 12, col. 3, par.2).

7. As per claim 3, Ware teaches wherein said domain is a condition experienced or perceived by said patient (Ware; pg. 12, Col. 3, para. 1-2).

8. As per claim 4, Ware teaches wherein the step of dynamically modifying includes the step of ranking said plurality of questions in accordance with said estimated score; and selecting a question from said plurality of questions based on said ranking that has not been administered to said patient (Ware; pg. 12, col. 1).

9. As per claim 5, Ware teaches wherein the step of selecting comprises selecting a highest rank question (Ware; pg. 12, col. 1).

10. As per claim 6, Ware teaches wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold (Ware; pg. 12, col. 1, para. 2-3).

11. As per claim 8, Ware does not expressly teach wherein the step of generating selects said questions for said domain from a database having questions and answers pertaining to a plurality of domains.

However this feature is well known in the art as evidenced by Lewis. In particular, Lewis teaches that a mastery testing procedure called the "Item Response Theory" (IRT) was well known in the art (Lewis; Col. 1, line 63 to Col. 10, line 7). The IRT guides the selection of questions or items for inclusion in an examination. Furthermore, the IRT is used to determine the number of test items answered correctly or incorrectly (Lewis; Col. 3, lines 25-55). It would have been obvious to add these

features to the Ware teachings with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

12. As per claim 9, Ware teaches wherein the step of administering includes the step of providing a list of possible answers for each question to said patient (Ware; Col. Pg. 13, Col.1-2).

13. As per claim 10, Ware teaches wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for errors or consistency (Ware; pg. 13, Col. 1-2).

14. As per claim 12, Ware does not expressly teach wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for estimating non-responsive answers to said test.

However this feature is well known in the art as evidenced by Lewis. In particular, Lewis teaches that a mastery testing procedure called the "Item Response Theory" (IRT) was well known in the art (Lewis; Col. 1, line 63 to Col. 10, line 7). The IRT guides the selection of questions or items for inclusion in an examination. Furthermore, the IRT is used to determine the number of test items answered correctly or incorrectly (Lewis; Col. 3, lines 25-55). It would have been obvious to add these

features to the Ware teachings with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

15. As per claim 13, Ware teaches wherein the step of reporting includes the step of comparing said answers provided by said patient with answers provided by other patients in said domain (Ware; Pg. 12, Col. 1-2 and Pg. 13, Col.1-2).

16. As per claim 14, Ware teaches administering includes the step of administering said test to said patients over a network, wherein said network is one of the following: an Internet, an intranet, a telephone network, and a wireless network (Ware; Pg. 12, Col. 3, par. 1-2).

17. As per claim 15, Ware teaches wherein the step of generating reports includes the step of generating said report over a network (Ware; Pg. 12, Col. 3, par. 1-2).

18. As per claim 17, Ware teaches wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, effectiveness of a treatment, physical health, emotional health, impact of asthma, job satisfaction, opinion polling, personality test, customer satisfaction and general overall health (Ware; pg. 12, Col. 1-3; pg. 13, col. 1-2).

19. Claims 18-23, 26-28, and 31-34 repeat the limitations of claims 1-6, 9-10, and 14-15 and 17 and the reasons for rejection are incorporated herein.

20. Claim 25 repeats the limitations of claim 8 and the reasons for rejection are incorporated herein.

21. Claim 30 repeats the limitations of claim 13 and the reasons for rejection are incorporated herein.

22. Claims 35-40 repeat the limitations of claims 1, 6, 17, and 18 and the reasons for rejection are incorporated herein.

23. As per claim 41, Ware does not expressly teach wherein at least two domains are selected to be assessed.

However, these features are well known in the art as evidenced by Lewis. IN particular, Lewis teaches both random and adaptive testlet selection are well known in the art (Lewis; Col. 6, "Random vs. Optimum Selection"). Lewis teaches that the method of assigning variable threshold variables to particular testlets. It would have been obvious to add these features to the teachings of Ware with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

24. Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), in view of Bair (6,067,523).

25. As per claims 42-45, Bair discloses:

(a) administering the test before a variable is introduced, wherein said variable includes a pharmaceutical such as Zoloft or Xanax, interventions or therapies (Fig. 1, 29-31,27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14);

(b) readministering the questionnaire after the variable is introduced (Fig. 1, 16, 29-31, 27B, col. 6 lines 11-21, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51); and

26. (c) comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy (see "patient satisfaction and assessing treatment in order to gauge the effect of the treatment upon the behavioral problem) or impact of the introduction of said variable on said health status or health care of said patient (Abstract; Fig. 29-31,27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51).

The motivation for including the features of Bair within the method and system of Ware being to assess treatment and patient satisfaction (Bair; col. 15 lines 20-30).

(10) Response to Argument

In the Appeal Brief filed 26 August 2008, Appellant makes the following arguments:

A) The combined references do not teach or suggest all the claim limitations.

B) There is no motivation to combine references.

The Examiner will address the arguments in the order that they appear in the Appeal Brief.

Argument A:

In response to the argument that the combined references do not teach or suggest all the claim limitations, Examiner disagrees.

(1) Applicant argues that as per claims 1-6, 8-23, 35-37, and 29-41, Ware in view of Lewis either taken alone or in combination teaches the limitation of "varying a threshold as a function of said estimated score." In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner notes that the "precision standard" described in Ware reads upon a "threshold." Applicant admits on pg. 13 of the 8/26/08

Appeal Brief that Ware sets different precision standards for different groups of patients (low vs. high scoring patients). Examiner submits that one of ordinary skill would understand that setting different precision standards for low vs high scoring patients reads upon "varying a threshold as a function of said estimated score."

Lewis further teaches the concept of "varying thresholds" in adaptive mastery tests. Lewis teaches the concept of varying a threshold as a function of a score with testlets (Lewis Col. 9, lines 5-10). Testlets are defined as a blocks of items. Lewis, Table 2 teaches that a threshold (Θn to Θm) varies as a function of the score of a testlet. Based upon the score the examinee is moves on to the next stage (reads upon "dynamically modifying said test…") In other words, an examinee will not be given another testlet unless the score does not fall within the "true mastery status" or "threshold." Thus, the combination of teachings in Ware and Lewis show that the "varying a threshold as a function of said estimated score" was old and well known in the art.

Applicant further argues on pg. 14 of the 8/26/08 Appeal Brief that Lewis actually teaches away from *adaptive* testing methods. Examiner disagrees. Although the random testlet method is a preferred embodiment, Lewis clearly states that both random and adaptive selection can be incorporated into a testlet methodology (Lewis; Col. 8, lines 55-60).

Applicant also argues that Lewis' solution for achieving its results is entirely opposite as proposed by the Applicant's claims. According to MPEP § 2106, USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003). Thus, Applicant focuses on mimicking the evaluation process performed by a professional health care provider but this not recited in the claims and given no patentable weight. The mere fact that Lewis deals with master testing in an educational context does not preclude it from reading upon Applicant's claims as they are given their broadest reasonable interpretation.

Argument B:

In response that as per claims 1-6, 8-23, 25-27, 29-41 and 42-45 there is no motivation to combine the references Examiner disagrees.

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case it is sufficient motivation to balance classification accuracy and test efficiency. In other words, classification accuracy and test efficiency are improved if the right questions quantity and quality of questions are administered in an exam.

In addition, as discussed in the *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct 1727 (2007), "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ('[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ" (emphasis added). Therefore, although Lewis does not expressly deal with mimicking the evaluation process of a health care provider Lewis still is relevant as

it deals with the related art of testing and self-assessments. Since the claimed invention is merely a combination of old elements, and in the combination each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(12) Notice to Appellant – Reply is Required

This examiner's answer contains a new ground of rejection set forth in section **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michelle Le /M. L./
Examiner, Art Unit 3686
Nov. 8, 2008

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686

Vincent Millin /VM/

Appeals Practice Specialist

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Wynn W. Coggins/

Director, TC 3600

Conferees:

Gerald O'Connor /GJOC/
Supervisory Patent Examiner
Tech Center 3600

Vincent Millin
Appeals Practice Specialist
Tech Center 3600

FULBRIGHT & JAWORSKI LLP
666 Fifth Avenue
New York, New York 10103

(212) 318-3000